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APPLICATION NO.	FI	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/825,210	(04/16/2004	Takahiro Ishikawa	24-014-TB	24-014-TB 7261	
23400	7590	07/24/2006		EXAMINER		
POSZ LAW		•		KRISHNAN, C	GANAPATHY	
12040 SOUT SUITE 101	HLAKE	SDRIVE		ART UNIT	PAPER NUMBER	
RESTON, V	A 20191			1623		

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)				
		10/825,210	ISHIKAWA ET AL.				
	Office Action Summary	Examiner	Art Unit				
		Ganapathy Krishnan	1623				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
2a) <u></u>	Responsive to communication(s) filed on 12 Ja This action is FINAL. 2b) This Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro					
Dispositi	on of Claims						
5)□ 6)⊠ 7)□	Claim(s) <u>1-6</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdrav Claim(s) is/are allowed. Claim(s) <u>1-6</u> is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/or	·					
Applicati	on Papers						
10)⊠	The specification is objected to by the Examine The drawing(s) filed on 16 April 2004 is/are: a) Applicant may not request that any objection to the Replacement drawing sheet(s) including the correction of the oath or declaration is objected to by the Ex	☑ accepted or b)☐ objected to be drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). lected to. See 37 CFR 1.121(d).				
Priority u	nder 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) □ All b) □ Some * c) ⊠ None of: 1. □ Certified copies of the priority documents have been received. 2. □ Certified copies of the priority documents have been received in Application No 3. □ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.							
2) 🔲 Notic	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail Da	ite				
	nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) No(s)/Mail Date	6) Other:	atent Application (PTO-152)				

Application/Control Number: 10/825,210

Art Unit: 1623

DETAILED ACTION

Claim Objections

Claim 4 is objected to because of the following informalities: Claim 4 recites sodium acetate as one of the Markush members for polar solvents. Sodium acetate is a salt and not a solvent. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the separation of glycolipids using a combination of chloroform, methanol, water and pyridine as solvents, does not reasonably provide enablement for the same for any and all other solvent combinations. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

- (A) The breadth of the claims
- (B) The level of one of ordinary skill

(C) The amount of direction provided by the inventor

(D) The existence of working examples

(E) The level of predictability in the art

(F) The quantity of experimentation needed to make or use the invention based on the

content of the disclosure.

The breadth of the claims

Instant claim 1 is drawn to a method of separating glycolipids comprising contacting a

sample solution via a semipermeable membrane with a solution having a lower osmotic pressure

till the sample solution separates into two or three layers and separating the middle and/or

bottom layer. The sample solution and the solution of lower osmotic pressure as instantly recited

are broad and are seen to include any solvent or combination of solvents.

The level of one of ordinary skill in the art

The level of skill of those in this art is that of one having experience in organic

synthesis/separation.

The amount of direction provided by the inventor

The instant specification is not seen to provide adequate guidance, which would allow the

skilled artisan to extrapolate from the disclosure and examples provided, to use the claimed

method commensurate in scope with the instant claims. There is a lack of data and examples that

adequately represent the claims as written.

The existence of working examples

The working examples set forth in the instant specification are drawn to extraction of

glycolipids from mice via dialysis of a sample solution wherein the sample solution comprises a

combination of chloroform/aqueous methanol and pyridine and wherein the solution of lower

osmotic pressure is distilled water. The sample solution already has three immiscible solvents to

Art Unit: 1623

begin with. One of ordinary skill in the art will not extrapolate this to a combination of any other solvent since the examples provided are not representative of any other solvent combinations encompassed by the broad recitation of instant claim 1.

The level of Predictability in the Art

Partitioning of samples can be partial or total and depends on the solvents used and the nature of the sample and its solubility differences in solvents used. Just because a sample is highly soluble in one solvent does not mean it will be soluble to the same extent in another similar solvent.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure

Indeed, in view of the information set forth, the instant disclosure is not seen to be sufficient to represent any or all solvent combinations encompassed by the recitation of the instant claims. One of ordinary skill in the art would have to carry out undue experimentation to practice the instant invention. One of ordinary skill in the art would be required to perform undue experimentation to determine which, if any, of the several solvent combinations would be useful to separate the glycolipids recited in instant claim 1.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites hydrolysis of an extract derived from a biological sample with a mixture of polar and non-polar solvents. It is not clear how using a solvent alone performs hydrolysis.

The claim recitation is unclear as to what applicants mean.

Conclusion

Claims 1-6 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/825,210

Art Unit: 1623

GK

Shaojia Jiang
Supervisory Patent Examiner
Art Unit 1623

Page 6